Plantar pressure: Comparing two Poron insoles

Andrew Cumming, Teresa Bayliff

Plantar pressure management in the neuropathic diabetic foot is an important element of ulcer prevention. The authors investigated two types of insole for their relative ability to redistribute plantar pressures in an older population with diabetes. No significant difference between the two insoles was found, but wearing either insole resulted in significantly improved plantar pressure distribution in comparison with wearing no insole.

Article points

1. People with diabetic peripheral neuropathy often experience changes in foot architecture, which may lead to the pathological redistribution of plantar pressures and, ultimately, to ulceration.
2. The authors assess two insoles for their effectiveness, in a group of people with diabetes, to redistributed peak plantar pressures during walking, and whether wearing either of the insoles was more effective than no insole.
3. No statistically significant difference in the mean plantar pressure during walking could be determined between the two insoles.
4. Further research is needed to define the place of insoles in the prevention of diabetic neuropathic ulceration.

Keywords

- Insole
- Neuropathy
- Plantar pressure
- Ulcer prevention

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People with diabetic peripheral neuropathy (DPN) often experience changes in foot architecture and the loss of protective sensation, both of which can lead to ulceration. One consequence of these neuropathy-related changes may be the pathological redistribution of plantar pressures (Frykberg et al, 2006).

A number of orthotic devices are available to protect at-risk areas of the foot (e.g. below the metatarsal heads) with DPN-related changes. The need for, and design of, orthotic devises to address DPN-related plantar pressure management is aided by devices that measure in-shoe plantar pressures. The best measurements of plantar pressure consider both total pressure and time, because the longer the period of time at which an area is under peak pressure, the more at risk of ulceration that area becomes (Cavanagh et al, 2001).

Bespoke, total-contact insoles made from foam impression boxes provide good pressure redistribution for the DPN foot (Bus et al, 2004; Tsung et al, 2004), but are often expensive. Off-the-shelf insoles are an inexpensive alternative that are appropriate in the management of plantar pressure in some people with DPN.

Detailed guidance on the provision of pressure-relieving insoles have been published by the American College of Foot and Ankle Surgeons (Frykberg et al, 2006) and Brem et al (2004). UK-based guidance (NICE, 2004; SIGN, 2010) also address this area. However, the evidence-base – especially in ulcer prevention, as opposed to prevention of ulcer recurrence – for insole use in this population is poor. Thus, there is a need to more fully understand the role of insoles in the prevention of diabetic foot ulceration, a condition associated with high morbidity and mortality (Gershater et al, 2009).

Here, the authors assess two types of 3-mm thick microcellular polyurethane insoles (Poron® 4400, a soft cushioning insole; Poron® 96, a slow memory, medical-grade insole; both Rogers Corporation, Woodstock, CT [distributed in the UK by Algeos, Liverpool]; *Figure 1*) for their effectiveness, in a group of people with diabetes, to redistributed peak plantar pressures during walking, and whether wearing either of the insoles was more effective than no insole.

Method

People attending a podiatry clinic in north

Birmingham were invited to participate in the study if they met the following inclusion criteria:

- Diagnosed diabetes (type 1 or type 2).
- An existing patient at the authors' podiatry clinic.
- Vascular and/or neurological impairment noted in a recent foot assessment (established using the standard assessment methods [NICE, 2004]).
- Over 18 years of age.
- Able to give informed consent and follow study protocol.
- Able to attend on two consecutive weeks for data collection.
- Able to walk for >10 m in the clinic without assistance (pressure measurement device requires this for data generation).
- Own suitable footwear (wide enough to fasten over the pressure measurement device without altering their gate).
- No previous insole treatment.
- No active foot ulceration.

Equal numbers of left and right Poron 96 and Poron 4400 insoles were made. Following enrolment, one left and one right insole were randomly allocated to each participant. Participants were advised to insert the insoles into a pair of everyday shoes and then increase the length of time that they wore the shoes with the insoles over a couple of days.

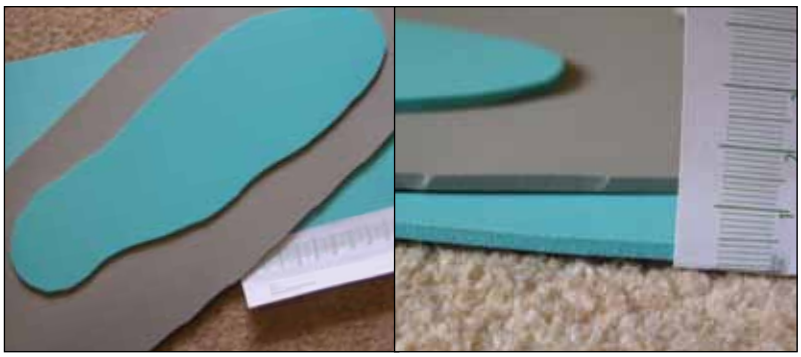

Figure 1. Examples of the insoles used. Poron 4000, a soft cushioning insole is grey; Poron 96, a slow memory, medical-grade insole is green.

Page points

1. After a week wearing their allocated insoles, each participant was invited back to the clinic and was assessed with a self-calibrating, in-shoe, pressure-recording device.
2. Twenty people participated in this study and had poor glycaemic control and were overweight. About half of the group has peripheral ischaemia and the majority had peripheral neuropathy.
3. The pressure redistribution achieved by Poron 96 reduced the mean pressure by 0.013 kg/cm^2/second more than Poron 4400. However, this difference was not statistically significant.
4. A number of authors have found that insoles are of use for the prevention of diabetic foot ulceration, although evidence is limited.

After a week, each participant was invited back to the clinic and was assessed with a self-calibrating, in-shoe, pressure-recording device (F-Scan®; Tekscan, South Boston, MA). The F-Scan has been found to be a reliable for measurements of high pressure and peak pressure in a population similar to the one in this study elsewhere (Ahroni et al, 1998). Each participant had eight recordings taken: four with the insoles in, and four without the insoles. Data were collected from seven areas on each foot (1st, 2nd, 3rd, 4th and 5th metatarsal–phalangeal joints; 1st interphalageal joint; heel).

Ethical approval was granted by the National Research Ethics Committee, Oxfordshire (Committee B). Local research and development approval was granted by the University of Warwick and by the Birmingham and Solihull PCT Consortium.

Statistics

Data were analysed using SPSS version 14 (IBM, Chicago, IL). Participant data were pooled and the mean for each measure determined. $P<0.05$ was considered statistically significant.

Results

Twenty people participated in this study (23 invited; three dropped out; 87% response). Participants were older (mean age, 68 years), had poor glycaemic control (mean HbA_{1c}, level 8.0% [64 mmol/mol]) and were overweight (mean BMI 30.6 kg/m^2). About half (55%, 11/20) of the group has peripheral ischaemia and the majority (90%, 18/20) had peripheral neuropathy (*Table 1*).

Poron 96 versus Poron 4400

The mean total pressure (all seven sites, left or right) when walking was 0.198 kg/cm^2/second wearing Poron 96, and 0.211 kg/cm^2/second wearing Poron 4400. Thus, the pressure redistribution achieved by Poron 96 reduced the mean pressure by 0.013 kg/cm^2/second more than Poron 4400. However, this difference was not statistically significant ($P=0.06$; *Table 2*).

Either insole versus no insole

The mean total pressure (all seven sites, left or right) while walking was 0.180 kg/cm^2/second while wearing either insole (either Poron 96 or Poron 4400), and 0.210 kg/cm^2/second when wearing no insole. A significant reduction in the mean pressure was seen during walking with an insole, as compared with no insole ($P\leq0.01$; *Table 3*).

Discussion

Owings et al (2009) remind us that plantar pressure management is only one factor in what should be a multifaceted strategy to prevent ulcer occurrence and recurrence in the diabetic foot. Yet, the relative contribution of increased plantar pressure in the natural history of neuropathic ulceration makes it a topic worthy of investigation in its own right.

A number of authors have found that insoles are of use for the prevention of diabetic foot ulceration, although evidence is limited and often based on case series

Table 1. Participant demographics.

Right foot dominant (*n*)	15
Average age (years)	68
Average BMI (kg/m^2)	30.6
Mean HbA_{1c} (%)	8.0† (SD±1.0)
Peripheral ischaemia‡ (*n*)	11
Peripheral neuropathy†† (*n*)	18

†64 mmol/mol. ‡Ankle–brachial pressure index <0.9. ††10-g monofilament text. SD, standard deviation.

Table 2. Statistical analysis of Poron 96 versus Poron 4000.

Paired differences					t	df	*P*-value
Mean	SD	SE mean	95% CI Lower	95% CI Upper			
0.01271	0.07844	0.00663	−0.00039	0.02582	1.918	139	0.06

CI, confidence interval; df, degrees of freedom; SD, standard deviation; SE, standard error.

rather than quantitative measurements. Given this, recommendations regarding the type and specification of insoles cannot yet be confidently made; a large, well-designed, randomised controlled trial comparing commonly used insole in ulcer prevention is awaited, and the outcome measures for such a trial should also encompass cost-effectiveness (Paton et al, 2011).

In the present cohort, no statistically significant difference in the mean plantar pressure during walking could be determined between Poron 96 and Poron 4400 insoles. The *P*-value approached significance and it is possible that the failure to achieve a statistically significant result was due to the small number of participants and the short run-in period. A small difference in the mean favoured Poron 96 and, although not statistically significant, this difference may yield clinical benefits.

The difference in mean plantar pressure during walking between either of the investigated insoles and no insole was statistically significant, and suggests that plantar pressure relief using off-the-shelf insoles is achievable. Whether this difference translates into a significant reduction in the incidence of ulceration in the neuropathic diabetic foot over time requires investigation.

Conclusion

This study revealed a difference in the mean total pressure redistribution achieved by two off-the-shelf insoles, but not a statistically significant one. However, the use of either insole revealed a significant improvement in plantar pressure when compared with no insole. Further research is needed to define the place of insoles in the prevention of diabetic neuropathic ulceration. ■

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Table 3. Statistical analysis of either Poron versus no Poron.

Paired differences					t	df	*P*-value
Mean	SD	SE mean	95% CI Lower	95% CI Upper			
0.02129	0.05459	0.00461	0.01216	0.03041	4.614	139	≤0.01

CI, confidence interval; df, degrees of freedom; SD, standard deviation; SE, standard error.